

# SPL Process ER/DL Meeting

## Meeting Minutes

### Nov 19, 2014

Chair of today's meeting: Pat Cowall

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

\*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

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Agenda:

1. Introductions: Herb O'Brien (Bayer) is joining Pat/Mary Beth as chair of this meeting.
  - Herb will be chairing the next meeting on Dec 3<sup>rd</sup>.
2. Other SPL efforts beyond labeling and drug listing: SPL Tech team will be hosting meetings to discuss these. Everyone is invited to attend:
  - SPL R7 and electronic Lot Distribution Report" – to be discussed on **Dec 15** by Vada Perkins, FDA
    - Current thinking on Lot Distribution Reports
    - SPL R7 will also be discussed – IDMP work
    - Lonnie is also discussing the data elements with the vendors
  - "SPL and REMS" – to be discussed on **Jan 26, 2015** by Adam Kroetsch, FDA
    - SPL Lead team is asking you to submit questions that you may have to topics that you want to discuss.
3. Kits that includes the 1) drug product in a multi-dose vial, 2) empty syringes, and 3) alcohol swabs. (Ruth Kirkner)
  - Are you aware of any products that are on the NLM Daily Med which fit that configuration?
  - Any guidance would be most appreciated.
  - People are handling this different ways:
    - One company has an example of a kit - betaseron" 50419-523-35. did not include alcohol swabs in the drug listing.

- Another company: Has included alcohol swabs as one of parts of the kit. OTC monograph final or not final. Kit with 2 parts: 1) vial and 2) alcohol swab. Not include device because nothing in it.
  - These would be combination products based on the kit – Type 1: convenience kit. co-packaged (empty syringe. Omit the empty syringe because it is a device.
  - Example on Daily med “xintha” - plasma derivative defined by CBER. Not a drug product. NDC 58394-012, 3 parts, with 3<sup>rd</sup> part is alcohol. Topical product – prep for injection site.
4. Second acknowledgement after SPL submission (Ruth Kirkner and Janet DeLuca):  
At the SPL Tech Q&A session on Monday morning at 11 am, 1<sup>st</sup> and 3<sup>rd</sup> Mondays, they discussed that as of this past weekend all SPL files submitted through the FDA ESG will now receive a second acknowledgement. This second acknowledgement should be opened to determine if the file was successful or not.

The following message was received in a second acknowledgement for a successful submission that has posted:

“The submission with core id \_\_\_\_\_ has successfully passed technical validation.”

- When you see this acknowledgement, you know whether it passed. It is not the dreaded 2<sup>nd</sup> acknowledgement.
  - How long does it take – within 10 minutes or so!
  - If it passed, then you know it is on its way to either NLM and to FDA’s database.
  - GDUFA – you will also get this also.
  - This applies to DERs and labeler codes too (not for new labeler codes because they need to assign a code).
5. Annual DER re-registration – D&B issues.
- Send any lingering issue to Lonnie Smith. He will forward your issue to John Gardner.
  - Several companies have completed their DERs.
  - However, there have been issues for UDIs which require DUNS information to be included.
  - Others have had issues – in particular with foreign companies.
  - Marcia will be sending out an on line survey to the SPL community to get feedback on their recent issues with D&Bs. Need as much information when there is an issue. Examples.
  - Please pay attention to the details as you work through your DERS - how long to resolve, how many hours of your time to resolve.
  - If we are selling a facility, will the DUNS number stay the same...or will it be different.
    - Dragan – when you sell, there should be a new number for the new legal entity.
    - Herb – when you purchase a new company, get a new number
    - Lilly/Hospira: Have experienced situations in which the DUNS numbers did not change.
    - Ruth will look into this and report back.
6. Dragan: Market a product and sold the NDA. But the bulk companies continue to use the same 3<sup>rd</sup> CM. Same product but multiple companies

- Who is responsible for “for export only” listing? The CM or the company that is marketing it? The manufacturing establishment is responsible for drug listing it for export only.
- Abbott is marketing it outside the US....but not in the US. So Abbott ultimately has a problem if there it doesn’t get listed.
- Charisse Kasser – “the sponsor” should take this responsibility, regardless of what the regs.

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#### REMINDERS:

- To accompany publication of the FDA’s draft “Guidance for Industry – Electronic Submission of Lot Distribution Reports,” an updated version of the SPL Implementation Guide/Validation Procedures document which includes a specific reference to the aforementioned guidance document has been posted: <http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM321876.pdf>.

- Sept 1, 2014 – Implementation of “Combination Product Type” data element for CDER-regulated products

Link to FAQs:

<http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm>

Definitions are available on the link from the SPL Resources page - SPL Terminology Files for Validation - [Combination Product Category Types](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm) (XML and Excel): open the xml/excel file)  
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

- DER Annual reporting period: Must be submitted for 2015 between October 1 and December 31, 2014.